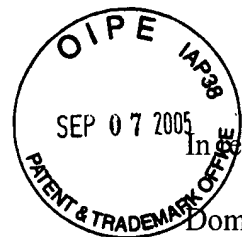


TSW



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

: **Mail Stop: Amendment**

Domenico FANARA et al.

: Docket No. 2003\_0894

Serial No. 10/607,047

: Examiner Not Yet Assigned

Filed June 27, 2003

: **Confirmation No. 4143**

PHARMACEUTICAL COMPOSITIONS FOR  
THE CONTROLLED RELEASE OF ACTIVE  
SUBSTANCES

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**PRELIMINARY REMARKS**

THE COMMISSIONER IS AUTHORIZED  
TO CHARGE ANY DEFICIENCY IN THE  
FEES FOR THIS PAPER TO DEPOSIT  
ACCOUNT NO. 23-0975

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The present paper is filed prior to issuance of the first Action in the above-identified continuation application.

Claims 11-25 are pending by submission of the Preliminary Amendment dated June 27, 2003.

In order to help establish the nonobviousness and patentability of the claimed invention over the prior art.

A Rule 132 Declaration is submitted concurrently herewith setting forth the experimental results.

In order to answer the Examiner's objection relating to the "specific drug" comprised in the formulation, an example with Trapidil, as active ingredient, is provided. Furthermore, there are some examples with various active ingredients (pseudoephedrine, trapidil, hydrocodone, efletirizine) in the patent application.

In order to answer the Examiner's objection relating to the "specific amounts of excipients" comprised in the formulation, examples made with pseudoephedrine as active substance but with various amounts of excipients are provided.

Applicants respectfully submit that these experimental examples will be suitable to overcome the Examiner's concerns.

These experimental results coupled with the experimental results which are set forth in the specification and in the Rule 132 Declaration filed April 28, 2003 clearly demonstrate the unexpected controlled release of active substance from the claimed pharmaceutical composition, commensurate in scope with the claims.

Accordingly, consideration and allowance is solicited.

Respectfully submitted,

Domenico FANARA et al.

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